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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,678	07/02/2003	Darrell C. Brett	ExpC:EptaRib	7367
26790	7590	01/10/2006		
LAW OFFICE OF KAREN DANA OSTER, LLC PMB 1020 15450 SW BOONES FERRY ROAD #9 LAKE OSWEGO, OR 97035			EXAMINER SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,678

Applicant(s)

BRETT

Examiner

david shay

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nove,ber 1, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 17 and 23-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

The double patenting rejection has been overcome due to the timely filing of a terminal disclaimer.

Applicant argues that claim 22 is enabled due to the mention of the performance of the calculation within the originally filed disclosure and in view of the fact that one having ordinary skill in the art to perform the calculation. The examiner must respectfully note that the assertion that one having ordinary skill in the art would be able to perform the calculation given the disclosure is a mere conclusory statement on the part of applicant's representative and as such does not provide evidence of the well known nature of such a calculation. Thus this argument is not convincing.

Next applicant argues that claim 4 is definite because the disclosure at page 17 of the originally filed disclosure discussed various energy applicators. This is noted, however, it is not an *energy application* layer that is claimed, but a *heat-generating* layer. Thus a lens, for example, even in conjunction with an energy source, would not generate heat per se, but would merely transmit the energy that would be converted to heat by the tissue itself. To the extent that applicant is attempting to claim the tissue as part of the heat generating layer, the claims are also directed to non-statutory material, as claiming part of the body and as such are hereby additionally rejected under 35 USC 101. Applicant's comments have only served to render even more unclear the metes and bounds of the claim, thus this argument is not convincing and the rejection has been maintained.

With regard to the art rejections, the Baker and Lax et al references employed in the rejections are indeed those discussed in applicant's remarks. With regard to the teachings of Baker, applicant's attention is respectfully invited to, for example Figure 2 of Baker to illustrate

the “elongated, relatively flat” construction of one of the electrodes therein, the flexibility of the electrode is discussed at column 7, lines 43-53, thus, as the electrode of Baker is elongated, relatively flat and flexible, it falls within applicant’s definition of “ribbon-like” also set forth at page 17 of the originally filed disclosure. Similarly the Lax et al reference, at Figures 2, 3, 7, 9, and 10 shows a layer, which is elongated and flat, while the flexibility thereof is demonstrated in Figure 5, for example, thus this element meets the “ribbon-like” limitation in the same manner as that of Baker. With regard to the limitations of claim 8, the antenna in Figures 7 and 10 of Lax et al and Baker, respectively would constitute a “bottom layer having a heat generator therein” to the extent such an element disclosed by applicant can. Also, with regard to the two references, those embodiments employing a liquid or gel conductive medium, which will inherently be a variable distance energy application region, by virtue of the fact that it flows, and thus would read on the argued limitations of claims 9, 13-16, and 18.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent as to the various factors needed and the manipulations thereof required for “calculating an amount of energy needed to refurbish thermally said at least one intervertebral disc.”

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because the exact meaning of the term “heat generation layer” is unclear.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Baker.

Baker teaches a thermal applicator which can include an insulative (protective) layer (see Figure 11), which can be used for annuloplasty (see Figures 15 and 16), and which when so used will deflect the dural sac and nerve roots on insertion. Since the device can expand and contract with temperature, it is considered expandable and contractible as claimed. Since the energy application surface in e.g. Figure 11 is an electrically conductive fluid or gel, the surface thereof will be a variable distance from the insulative layer.

Claims 1-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Baker.

Lax et al teaches a thermal applicator which can include an insulative (protective) layer (see Figure 9), which can be used for annuloplasty (see Figures 22 and 23), and which when so used will deflect the dural sac and nerve roots on insertion. The device can also have a dome shape (see Figure 10). Since the device can expand and contract with temperature, it is considered expandable and contractible as claimed and since the expansion will be in proportion to the temperature rise, the distance will be automatically and mechanically variable in proportion to the amount of energy being delivered. Since the energy application surface in e.g.

Figure 9 is an electrically conductive fluid or gel, which is under physician control (see Figure 11) the surface thereof will be a manually variable distance from the insulative layer

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lax et al. in combination with Danon and Coleman. Lax et al teach a device and method such as claimed, as set forth above. Danon teaches a surgical system wherein a predictive element determines and displays the determined results of the next application of treatment energy prior to administering the energy. Coleman teaches measuring the amount of tissue shrinkage based on measurements of untreated tissue and the energy applied. It would have been obvious to the artisan of ordinary skill to employ a device and method as taught by Danon in the device and method of Lax et al, since this would provide greater patient safety and to employ the data of Coleman to make the determination of Danon, since Danon gives no means by which this determination can be made, thus producing a method such as claimed.

Claims 17 and 23-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed November 1, 2005 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

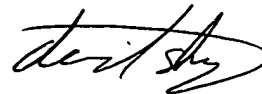
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam, can be reached on Monday, Tuesday, Wednesday, and Thursday at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
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